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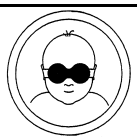
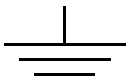
DISCLAIMER

The safety devices and other controls provided in this equipment will perform reliably when operated, maintained, and repaired in accordance with the instructions of this manual.

Safety devices must be checked periodically and reset, repaired, or replaced as necessary to ensure that they will operate reliably. Equipment and parts that are broken, missing, badly worn, distorted or contaminated should be replaced with appropriate GUIDO RAYOS X parts. The equipment or its components should not be modified without the approval of the manufacturer.

The Manufacturer disclaims all responsability for any malfunction of this equipment resulting from faulty operation, maintenance or repair, or if any of its components are damaged or modified by anyone other than the manufacturer.

SYMBOLS CHART

SYMBOL	DESCRIPTION
	In compliance with the requirement of the Medical Devices Directive 93/42/EEC. Certified by notified body no. 0120
	Alterning current
	Atention, read the attached documents
	Fuse
	Off
	On
	Patient eyes protection
	Earth
	Class I, Type B Equipment
	Electrical waste. Selective collection

SPECIFICATIONS

Description	Phototherapy
Model	NESTOPHOT
Power	External AC 230 V 50/60 Hz 1,5 A 100 W
Electric isulation	Class : I Type : B
Incoming water protection	Ordinary (IPX0)
Operation mode	Continuos
Fuses	2 slow fuses 2 A 5x20 mm
Measurement	Mounting: height 1,40 m foot : 59x47 y 27x47 Lamp unit: 60x30 cm
Wavelenght	range 460 nm (blue specter)
Thermal power	4 lamps 18 w each
Radiation	8,3 ìW/cm^2/nm at 80 cm from light source 19,7 ìW/cm^2/nm at 50 cm from light source
Storage and handling conditions	Temperature -10ºC to +40ºC Humidity : 10% to 90%
Noise level	Less than 40 dBa

WARNINGS

Generals

- It has not been detected anomalies in the operation of the equipment by the effect of external electromagnetic interferences, such as mobile phones, laptops, etc.
- It has not been detected any alteration in the operation of the equipment by variation of the environmental conditions
- It has not been detected injurious effects of the equipment on the patient nor on the operator. Despite of it, the use of protective goggles or screens is recommended.
- It has not been detected any perturbation in the water balance of the patient by effect of the lamps of cold light.
- Monitor bilirrubin values according to the indications of the medical facultative.
- Do not use NESTOPHOT equipment in combination with flammable products, such as cleaning or antiseptic agents
- Do not store medicaments nor infusion liquids into radiation area
- Do not use NESTOPHOT equipment in the presence of gases that can help the combustion
- Do not use two or more phototherapy units together nor adjacent
- Carry the equipment holding the vertical bar. Do not push the frontal nor the back of the lamps module to transport.

In chapters

I
- Bilirubin photoisomer can cause detrimental effect in the patient
- NESTOPHOT uses cold light lamps, so its use do not increase patient temperature
- This equipment can be used in combination with a thermotherapy device, without affecting the temperature of the patient. So, the use of skin temperature sensor is not indispensable.

II - Cover infant's eyes to protect from high light levels.

V - The fluorescence lamps must be collected according the current legislation.

- The substitution of the lamps must be made only by authorized qualified personnel.
- The use of lamps others than recommended (DULUX ® L lamps) can affect both the security and the effectiveness of the equipment.

I. PRELIMINARY

Intended use

Bilirrubin is produced primarily in the decomposition of red blood cells; it becomes water-solubles in the liver through combination with glucuronic acid and thus be separated (through the bile).

If an icterus occurs on the first day of the newborn infant, treatment to reduce the bilirubin is necessary. The phototherapy method has predominated as a reliable method. Through a photochemical reaction, light changes insoluble bilirubin into the water-soluble form, permitting removal through the bile and urine without coupling to the glucuronic acids in the liver. For an effective treatment at least 4 ìW/cm^2/nm of radiant flux is required.

NOTE : bilirubin photoisomer can cause detrimental effect in the patient

NESTOPHOT phototherapy unit emits 8 ìW/cm^2/nm exactly in 460 nm range to reduce the treatment duration and, consequently, increase lamps life. This turns it to an extremely suitable instrument for bilirubin treatment

NOTE: NESTOPHOT uses cold light lamps, so its use do not increase patient temperature

NESTOPHOT equipment is provided with an electric clock for total operation time and an electric clock for treatment time with zero reset. NESTOPHOT has four castors to its better mobility.

NOTE : this equipment can be used in combination with a thermotherapy device, without affecting the temperature of the patient. So, the use of skin temperature sensor is not indispensable.

II. OPERATION

To turn on the Phototherapy Unit, just press the **I/O** switch.

WARNING : Cover infant's eyes to protect from high light levels.

Reset the clock to zero when starting the treatment, to know the exact time for each patient.

The total time clock will inform the total time that the Phototherapy is being used. In such way the user will know how long the lamps have been operating.

When the treatment time is over or any time the operator wants to interrupt the treatment, press **I/O** to switch off the unit.

When installed at a mobile stand, the shroud height can be adjusted. For such purpose, hold tightly the stand upper bar and loose by turning counterclockwise the locker placed on top of the stand lower bar. Slide upwards or downwards the phototherapy assembly and then turn tightly clockwise the locker. Check the stand bar is duly secured.

The **NESTO**PHOT shroud can be positioned in vertical, if required. Turn the shroud to place at the required position (a ball-and-socket joint allows the manoeuvre) and adjust the height as explained here above.

III. LAMPS

NESTOPHOT comprises four DULUX ® L lamps, specially designed for this kind of treatment.

The lamps emit at 8 ìW/cm^2/nm, measured at 80 cm distance. For an effective treatment, 4 ìW/cm^2/nm are required at least.

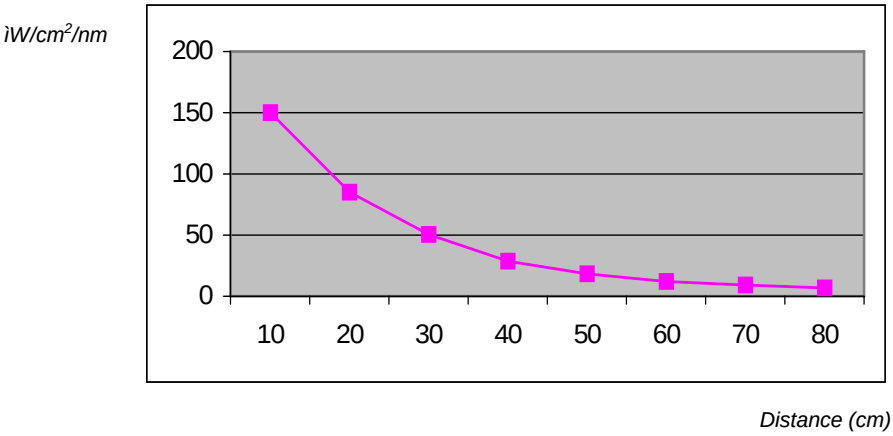


Fig 1. Total irradiance for bilirrubin and its dependency with the distance

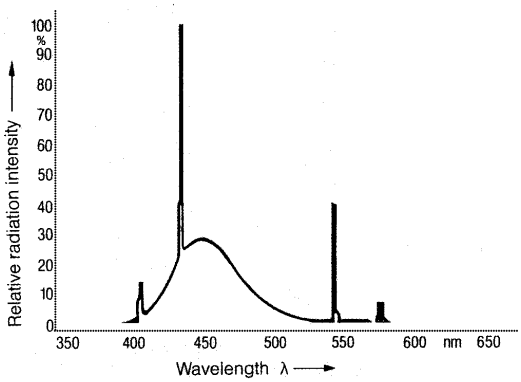


Fig 2. Average spectral irradiance for wavelengths from 320nm to 550nm

After operation hours the lamps lose gradually their output power, being recommended to check periodically the radiation power with the appropiate measuring equipment. When radiation drops below 4 ìW, the lamps should be replaced as indicated in chapter MAINTENANCE AND CLEANING

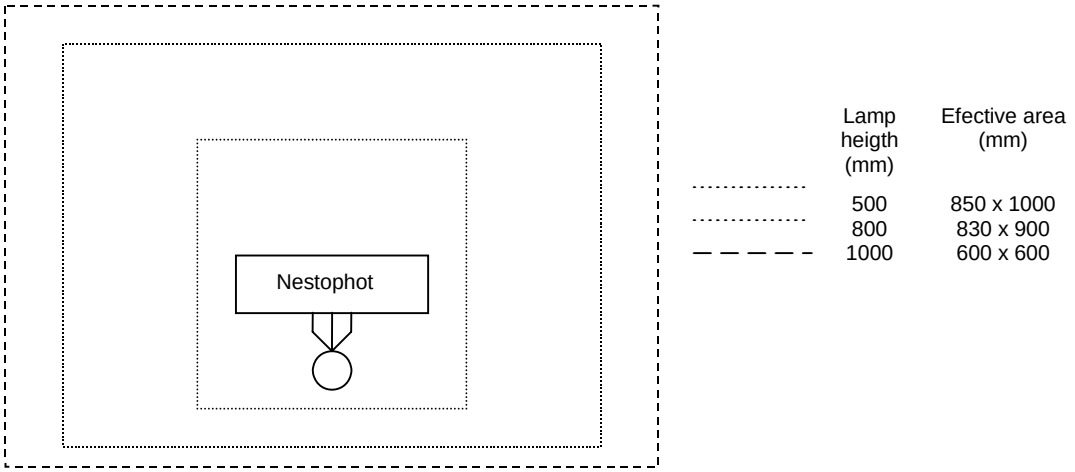


Figure 4.3 - *Radiation area depending on lamp heigth*

IV. INSTALLATION INSTRUCTIONS

Inside the crate the following parts are packed separately:

PHOTOTHERAPY UNIT

STAND, UPPER AND LOWER BARS

MOBILE BASE

To assembly above parts proceed as follows:

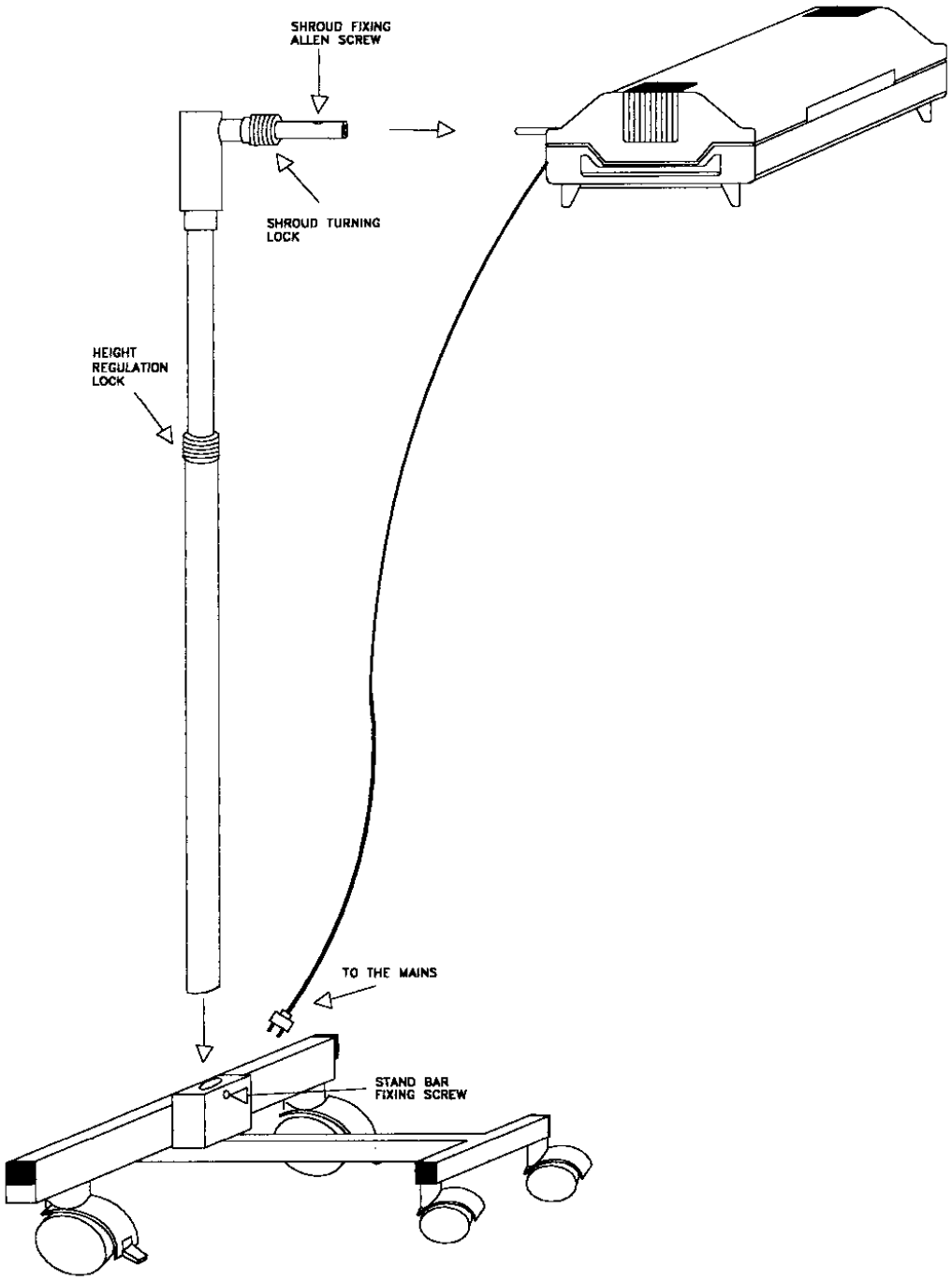
- Unpack carefully each part.
- Place the large diameter bar into the hole at the mobile base.Insert the thiner bar into the large diameter bar.

  IMPORTANT: The groove of the thiner bar must be oriented backwards the mobile stand assembly.

- Then, secure tightly the allen screw (an allen key is enclosed within the equipment) to avoid the bar could be rotated or pulled out from the wheeled base.
- Insert the Phototherapy unit into on the mobile stand, matching both in order to fasten them by means of the allen screw. Screw must be tightly secured.

(See following drawing)

ASSEMBLY


SHROUD FIXING ALLEN SCREW
SHROUD TURNING LOCK
HEIGHT REGULATION LOCK
TO THE MAINS
STAND BAR FIXING SCREW

V. MAINTENANCE AND CLEANING

Guido Rayos X, S.A., will provide under request any schemes of the circuits, listings of components, descriptions, instructions of calibration and other information that help suitably technical personnel to repair those parts of NESTOPHOT equipment designated by the manufacturer as repairable

> **ATTENTION** : the fluorescence lamps must be collected according the current legislation.

Lamps substitution

> **ATTENTION** : The substitution of the lamps must be made only by authorized qualified personnel

To replace the lamps, proceed as follows:

1. Unplug the power cord from the mains. Switch must be on **O** position
2. Loose the screws placed on the top of the shroud
3. Remove carefully the shroud top
4. Loose and remove upwards the lamps rack
5. Remove carefully the lamps holding them tightly
6. Install and secure the new lamps into their fittings
7. Place the lamps rack into the shroud
8. Replace the shroud top
9. Screw the shroud top
10. Plug the power cord
11. Turn on the unit to test its performance

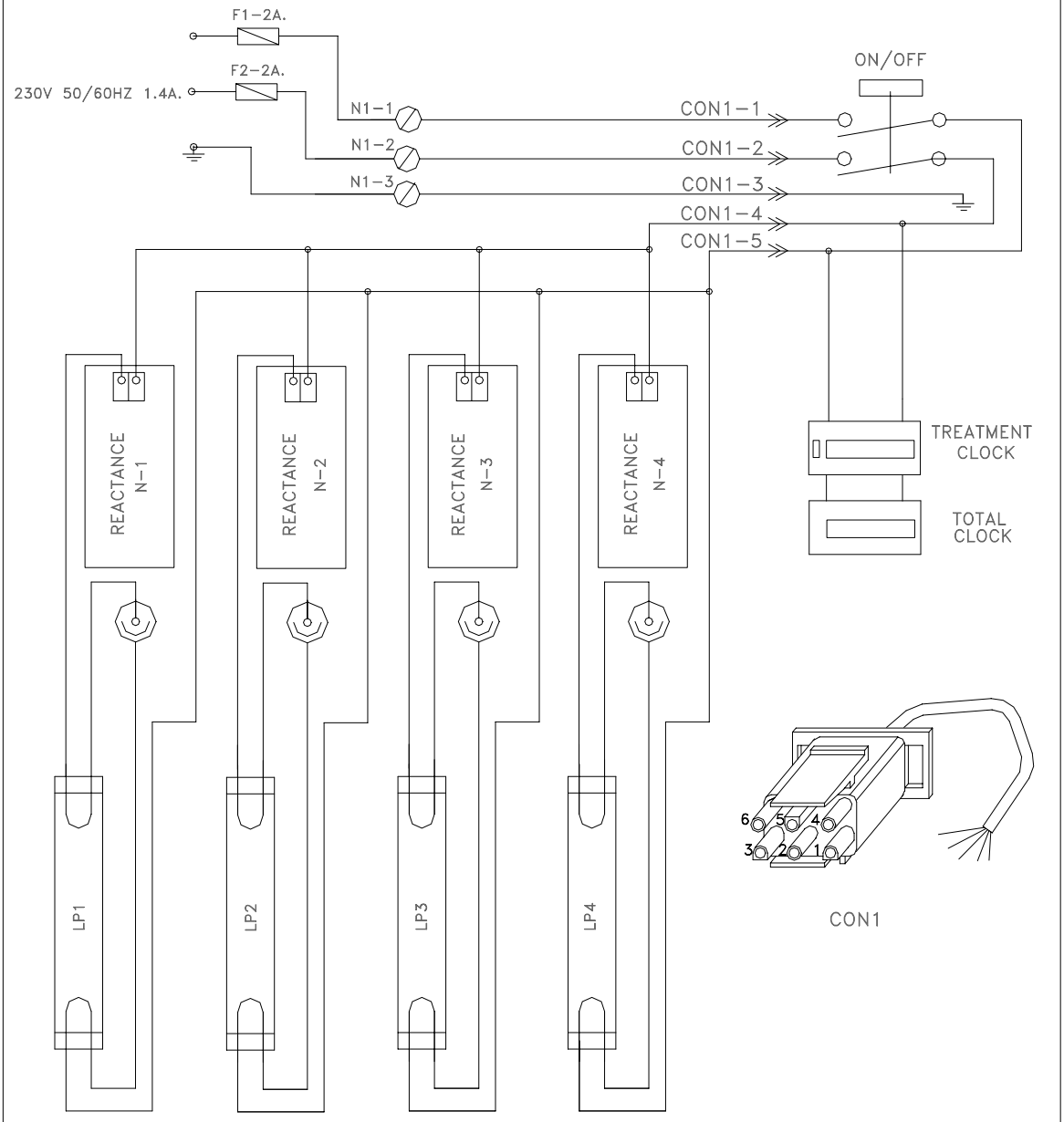
> **ATTENTION** : the use of lamps others than recommended (DULUX ® L lamps) can affect both the security and the effectiveness of the equipment.

Cleaning

For routine cleaning, the entire unit may be wiped with a mild soap and water solution. Avoid scratching painted surfaces.

Do not use any cleaning agent containing an abrasive material. When sterilization of exterior parts is necessary, wipe those parts with a cold sterilization agent not including alcohols or ethers.

ELECTRIC DIAGRAM



GUIDO RAYOS X S.A. (Madrid)	Fecha:	Nombre:	Material:	Referencia:	Tolerancias:
	Dibujado: 17–3–2004	J.Ruiz			
	Comprobado:				
	Autorizado:			N° Plano:	0242/5
Escala:	Denominacion: PHOTOTERAPY DIAGRAM 125/230V 50/60HZ			Sustituye a:	0242/4
				Sustituido por:	

SPARE PARTS LIST

COMPONENT	QUANTITY
WASHER DIN 125 NYLON 3,5 MM	6
WASHER DIN 127 M5 GROWER	4
FLEX CORD 1 MM BLUE	2 M
FLEX CORD 1 MM BLACK	2 M
FLEX CORD 1 MM GREEN	1 M
GROUND CORD GREEN-YELLOW 1MM	1,5 M
CONNECTOR 6 PIN FEMALE	1
CONNECTOR 6 PIN MALE	1
PLASTIC CLAMP BIG	10
PLASTIC CLAMP SMALL	25
BLACK SWITCH ON	1
LAMP DULUX-L 18/71 PHOTOTHERAPY	4
5 CONNECTIONS STRIP	1
FASTON TERMINAL FEMALE 6,3 MM WITH HOLD	6
FASTON TERMINAL MALE 6,3 MM WITH HOLD	6
FEMALE TERMINAL BLUE BF-F608-P	4
OPEN TERMINAL BLUE BF U4	1
ROUND TERMINAL BLUE BK M4	1
ROUND TERMINAL RED RF M3	1
OPEN TERMINAL RED RF U4	7
SCREW DIN 913 M6X16 FIXED	1
SCREW DIN 916 M6X8	4
SCREW DIN 965 M3X20	2
SCREW DIN 7985 M3X8	10
SCREW DIN 7985 M4X6	4
SCREW DIN 7985 M4X8	4
SCREW DIN 7985 M4X10	8
SCREW DIN 7985 M5X10	8
SCREW DIN 7985 M5X20	4
SCREW DIN 7985 M6X10	2
THERMICAL RETRACTILE TUBE 2MM	0,5
NUT DIN 934 M3	10
NUTSER NUT M4	12
WASHER DIN 6799 M3	8
ALUMINUM ROD WITH CHANNEL 80 CM	4
NESTOPHOT BASE	2
SUBJECTION RACK	1
CABLE WITH POWER BOLT 3M 3X15	1 M
INFERIOR ENVELOPE CARCASS	1
SUPERIOR ENVELOPE CARCASS	1
SOCKET 25X35	2
STARTER 15/20 W	4
TUBE CLIP	4
PROFILE REGULATION SYSTEM NESTOPHOT	1

COMPONENT	QUANTITY
Slow fuse 2 A	2
NESTOPHOT transparent plastic	1
Starter holder	4
Fuse holder 5x30	2
Tube holder	8
Reactance 15/20 W 230 V	4
Digital clock	2
Castor M10 with brake	1
Castor without brake	2
Tube holder shell, right	1
Tube holder shell, left	1
Upper shell	1
Nestophot rack cover	1
Tube cover 40x40	1
Tube 40x36mm 1 meter, Nesto shell	1
Nutser screw M3	4
Nutser screw M8	2

WARRANTY

GUIDO RAYOS X S.A. (hereinafter referred to as GRX) warrants that each **NESTO**PHOT will be free from defects in material and workmanship under normal use and service for a period of one year from the date of delivery by GRX to the first purchaser. If any such defect occurs during the warranty period, the aforesaid purchaser should communicate directly with GRX agent. If returned, GRX's agent will arrange for repairs or replacement within the terms of warranty. The defective instrument should be returned properly packed, freight prepaid. Loss or damage in shipment to GRX agent shall be at purchaser's risk. This same warranty is made for a period of thirty days with respect to the expandable parts.

In no event shall GRX be liable for any incidental, indirect, or consequential damages in connection with the purchase or use of the unit. This warranty shall not apply and GRX shall not be responsible for any loss arising in connection with the purchase or use of any unit wich has been altered by anyone other than an authorized GRX representative or altered in any way that, in GRX's judgement, affects its stability or reliability or wich has been subject to misuse, negligence, or accident, or wich has been used otherwise than in accordance with the instructions furnished by GRX. This warranty is in lieu of all other warranties, express or implied, and of all other obligations or liabilities on GRX's part, and GRX neither assumes or authorizes any representative or other person to assume for it any other liability in connection with the sale of such unit.

GRX disclaims all other warranties, express or implied, including any implied warranty of merchant ability or of fitness for a particular purpose or application other than those expressly set forth in the appropiate product labelling or user information manual.

CERTIFICATIONS

The quality system of GUIDO RAYOS X, S.A. has been audited and certified by SGS United Kingdom, Ltd for its compliance with the requirements of standards ISO 9001: 2000 and ISO 13485 : 2003

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CE 0120

Phototerapy Unit

NESTOPHOT

Serial number :

User's and Service Manual